K002885

JUN 2 1 2001

510(k) Premarket Notification

Dade® PFA-100® Platelet Function Analyzer
Dade® PFA Collagen/Epinephrine Test Cartridge
Dade® PFA Collagen/ADP Test Cartridge
Dade® PFA Trigger Solution
September 14, 2000

Dade Behring Inc.
7739 NW 48th Street
Miami, FL 33166
Contact Person: Radames Riesgo at 305.392.5639 or by facsimile at 305.392.5638.

Trade or Proprietary Name: Dade® PFA-100® Platelet Function Analyzer
Dade® PFA Collagen/Epinephrine Test Cartridge
Dade® PFA Collagen/ADP Test Cartridge
Dade® PFA Trigger Solution

Common or Usual Name: Platelet function analyzer

Classification Name: Automated platelet aggregation system
(21 CFR § 864.5700)

Registration Number:

Manufacturing Site (Reagents)
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
Marburg, Germany 9610806

Manufacturing Site (Instrument)
Dade Microscan Division
2040 Enterprise Blvd.
West Sacramento, CA 95691 2919016

Distributor
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101 2517506

The Dade® PFA-100® Platelet Function Analyzer is an *in vitro* diagnostic system intended as an aid in the detection of platelet dysfunction in citrated human whole blood.

The labeling of the diagnostic system has been modified to include a summary of the results of the clinical studies conducted using pediatric population.

Two separate clinical studies were conducted by independent organizations. In one study, the closure times (CT's) with Col/EPI and Col/ADP cartridges of 57 ostensibly healthy children, with an age range of 5 to 17 years, were consistent with the CT's of 31 healthy adults (age range of 25 to 54 years). In the other study, 41 children (age range of 1.5 to 18 years) with VWD (17 with types 2 or 3 and 24 with definite type 1) were tested. Of these children, 36 had abnormal CT's with Col/EPI cartridges and 37 had abnormal CT's with Col/ADP cartridges. Four children with definite type 1 VWD had normal CT's with both cartridge types and also showed normal levels of VWF:Ag and VWF:RCo on the same day of PFA testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 1 2001

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
Dade Behring, Inc.
Glasgow, Business Company
Building 500, Mailbox 514
P.O. Box 6101
Newark, Delaware 19714-6101

Re: K002885
Trade Name: Dade® PFA-100 Platelet Function Analyzer
Regulation Number: 21 CFR § 864.5700
Regulatory Class: II
Product Code: JOZ
Dated: May 9, 2001
Received: May 10, 2001

Dear Mr. Riesgo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002885

Device Name: Dade® PFA-100 Platelet Function Analyzer

Indications for Use:

To aid in the detection of platelet dysfunction in citrated human whole blood for use in patients with a suspected disorder of primary hemostasis.

(Sign-Off)
of Clinical Laboratory Devices
Number K002885/S2

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**